

Exhibit 7

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	CONFIDENTIAL –
	:	FILED UNDER SEAL
v.	:	
	:	
CIPLA LTD., AUROBINDO PHARMA	:	
LLC, AUROBINDO PHARMA USA,	:	
INC., and AUROLIFE PHARMA LLC,	:	
	:	
Defendants.	:	
	:	

**PLAINTIFFS TEVA PHARMACEUTICAL PRODUCTS R&D,
INC. AND NORTON (WATERFORD) LTD.'S PROPOSED
PRETRIAL FINDINGS OF FACT**

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I. Introduction¹

1. This is a consolidated action for patent infringement under Title 35, U.S. Code, brought pursuant to the Hatch-Waxman Act, by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, “Teva”) arising out of the filing by each of Defendants Cipla Ltd. (“Cipla”) and Aurobindo Pharma LLC, Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, “Aurobindo”) of an Abbreviated New Drug Application (“ANDA”), seeking approval to market generic versions of Teva’s Qvar® 40 mcg and 80 mcg (beclomethasone dipropionate HFA 40 mcg and 80 mcg) Inhalation Aerosol products prior to the expiration of U.S. Patent Nos. 9,463,289 (the “289 Patent”), 9,808,587 (the “587 Patent”), and 10,561,808 (the “808 Patent”).

2. Teva is the holder of New Drug Application (“NDA”) No. 20911 for Qvar®. Teva’s Qvar® inhalers are approved by FDA for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.

3. Teva is the owner and assignee of all patents-at-issue, and those patents have been listed in connection with Qvar® in FDA’s Orange Book.

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). This Court has authority to grant declaratory relief under 27 U.S.C. §§ 2201 and 2202.

5. Defendants do not dispute jurisdiction and venue.

II. Procedural History

6. Defendants filed ANDAs with Paragraph IV certifications to the patents listed in paragraph 1.

7. Teva filed suits alleging that Defendants’ ANDA filings with Paragraph IV certifications constitute acts of infringements. These cases were consolidated.

¹ Many of these statements respond to Defendants’ assertions in their pretrial submissions. By including these statements in this Proposed Pretrial Findings of Fact, Teva does not admit that the issue has not or cannot be proven as a matter of law.

8. Each Defendant, answered, denying infringement and alleging invalidity. Defendants filed counterclaims seeking declarations of non-infringement and invalidity.

9. Plaintiffs will assert at trial the following claims against Defendants (collectively, the “Asserted Claims”):

- Claims 1-8 of the ’289 Patent;
- Claims 1-8 and 11-22 of the ’587 Patent; and
- Claims 1, 27, and 28 of the ’808 Patent.

III. Person of Ordinary Skill in the Art (“POSA”) and Priority Date

10. The person of ordinary skill in the art (“POSA”) for the Asserted Claims would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included individuals with master’s degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor’s degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. The team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices.

11. The Asserted Claims of the ’289, ’587, and ’808 Patents are entitled to a priority or critical date of no later than May 18, 2009; alternatively November 5, 2009; alternatively, no later than December 2, 2009; alternatively, no later than March 16, 2010 (in the case of the ’808 Patent only); alternatively, no later than May 18, 2010, the date on which U.S. Provisional Patent Application No. 61/345,763 was filed; alternatively, no later than November 29, 2010, the date on which U.S. Provisional Patent Application 61/417,659 was filed; and alternatively, no later than May 18, 2011, the date on which U.S. Patent Application No. 13/110,532 was filed.

IV. Infringement

A. The '289 Patent

1. Claim 1

12. Defendants' ANDA Products satisfy every limitation of claim 1 of the '289 Patent.

13. Claim 1 recites as follows:

1. An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

a. "Inhaler for Metered Dose Inhalation"

14. Defendants' ANDA Products are "inhalers for metered dose inhalation." See, e.g., PTX-081 (CIPLA-BDI_0000635 (Cover Letter)

(“Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg and 80 mcg”)); PTX-093 (CIPLA-BDI_0155972, at -974 (Proposed Labeling) (“Inhalation Aerosol: Beclomethasone dipropionate HFA, inhalation aerosol is a pressurized, metered-dose aerosol with a dose counter intended for oral inhalation . . .”)); PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); PTX-035 (AURO_BECL00000121 (Cover Letter) (“Beclomethasone Dipropionate HFA, 40 mcg and 80 mcg Inhalation Aerosol”)); PTX-036 (AURO_BECL00000146, at -150 (Proposed Labeling) (“Inhalation Aerosol: Beclomethasone dipropionate HFA inhalation aerosol is a pressurized, metered-dose aerosol with a dose counter intended for oral inhalation . . .”)); PTX-315 (AURO_BECL00005976-77 (Design Drawings)); PTX-409 (Aurobindo ANDA Product Sample); PTX-410 (Aurobindo ANDA Product Sample); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

b. “A Main Body Having a Canister Housing”

15. Defendants’ ANDA Products comprise “a main body having a canister housing.” The parties have agreed that the term “canister housing” should be construed to mean “the portion of the inhaler body that is arranged to retain a medicament canister.”

16. Defendants’ ANDA Products comprise medicament “canisters.” *See, e.g.*, PTX-308 (CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report)); PTX-093 (CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling)); PTX-094 (CIPLA-BDI_0156595, at -595, -597 (Photographs)); PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); PTX-036 (AURO_BECL00000146, at -150, 174-76 (Proposed Labeling)); PTX-040 (AURO_BECL00001277, at -1286-87 (Pharmaceutical Development)); PTX-330 (AURO_BECL00005711, at -5767 (Container Closure System)); PTX-409 (Aurobindo ANDA Product Sample); PTX-410 (Aurobindo ANDA Product Sample); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

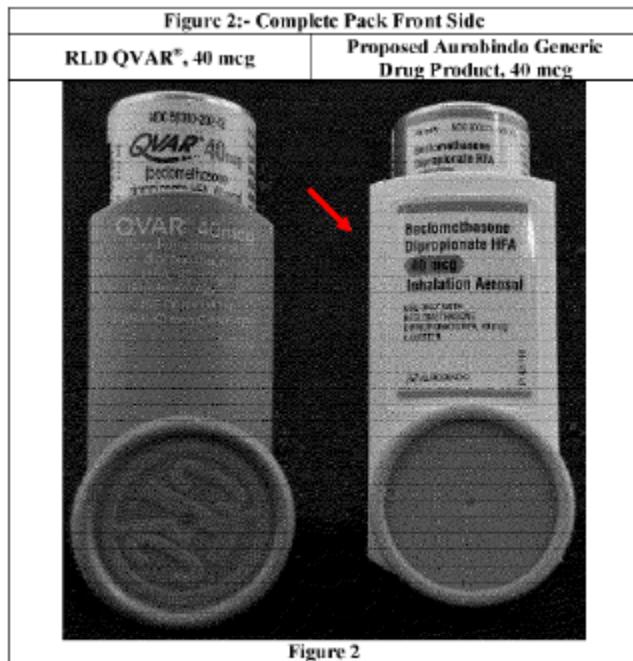
17. Defendants’ ANDA Products further comprise “main bodies” (i.e., what Defendants refers to as “actuators”). Defendants’ main body has a portion which is arranged to retain a medicament canister.

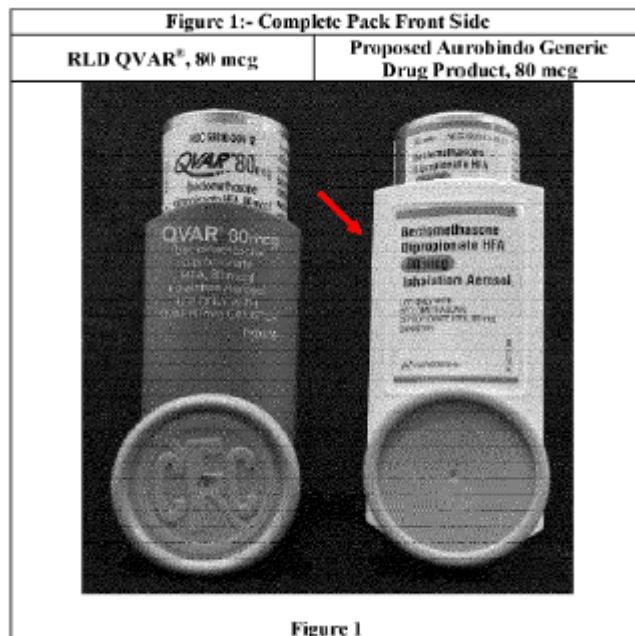
Cipla



See, e.g., PTX-094 (CIPLA-BDI_0156595, at -595, -597 (Photographs)); see also PTX-308 (CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report)); PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

Aurobindo





See, e.g., PTX-040 (AURO_BECL00001277, at -1286-87 (Pharmaceutical Development)); *see also* PTX-036 (AURO_BECL00000146, at -150, 174-76 (Proposed Labeling)); PTX-330 (AURO_BECL00005711, at -5976 (Container Closure System)); PTX-046 (AURO_BECL00803513-14); PTX-318 (AURO_BECL00803466 (Design Drawings)); PTX-409 (Aurobindo ANDA Product Sample); PTX-410 (Aurobindo ANDA Product Sample).

18. At his deposition, Cipla's corporate representative confirmed that Cipla's ANDA Product (which is materially similar to Aurobindo's ANDA Product) satisfies this limitation. *See, e.g.*, Rote Dep. Tr. 47:5-7.

19. [REDACTED]

20. Both Cipla's and Aurobindo's ANDAs refer to the same drug master files ("DMFs"), and there are no material differences between the Defendants' products. *See, e.g.*, PTX-034 (AURO_BECL00000014 (Form 356h)); PTX-330 (AURO_BECL00005711, at -5976-77 (Container Closure System)); PTX-046 (AURO_BECL00803513-14); PTX-318 (AURO_BECL00803466 (Design Drawings)); PTX-080 (CIPLA-BDI_0000004 (Form 356h)); PTX-308 (CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report)); PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); PTX-409 (Aurobindo ANDA

Product Sample); PTX-410 (Aurobindo ANDA Product Sample); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

c. “A Medicament Canister, Which Is Moveable Relative to the Canister Housing and Retained in a Central Outlet Port of the Canister Housing Arranged to Mate with a Canister Fire Stem of the Medicament Canister”

21. Defendants’ ANDA Products comprise “a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister.”

22. Defendants’ ANDA Products comprise a medicament canister. *See, e.g.*, PTX-093 (CIPLA-BDI_0155972, at -974, 996-98 (Proposed Labeling)); PTX-308 (CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report)); PTX-094 (CIPLA-BDI_0156595, at -595, -597 (Photographs)); PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); PTX-036 (AURO_BECL00000146, at -150, 174-76 (Proposed Labeling)); PTX-040 (AURO_BECL00001277, at -1286-87 (Pharmaceutical Development)); PTX-330 (AURO_BECL00005711, at -5767 (Container Closure System)); PTX-409 (Aurobindo ANDA Product Sample); PTX-410 (Aurobindo ANDA Product Sample); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

23. Defendants’ ANDA Products have a canister fire stem.

Cipla

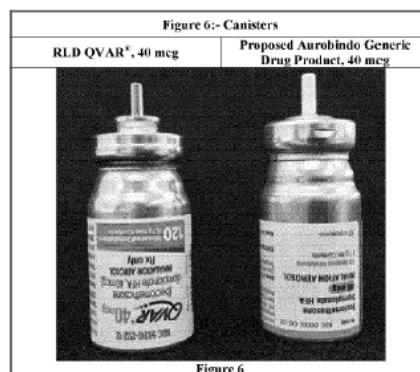
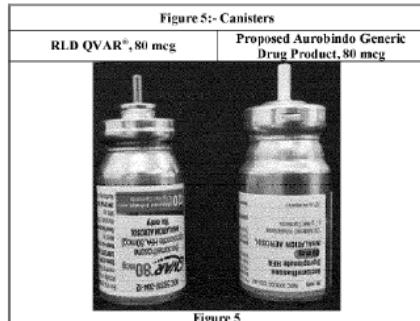


See, e.g., PTX-094 (CIPLA-BDI_0156595, at -597 (Photographs)); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).



PTX-094 (CIPLA-BDI_0156595, at -595 (Photographs)); see also PTX-308 (CIPLA-BDI_0004411, at -637 (Pharmaceutical Development Report)); PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

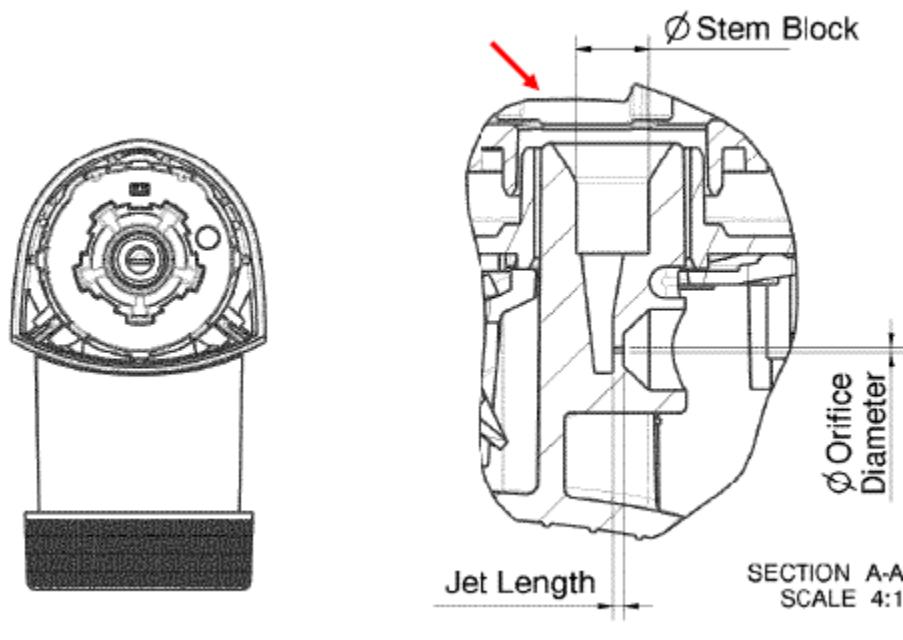
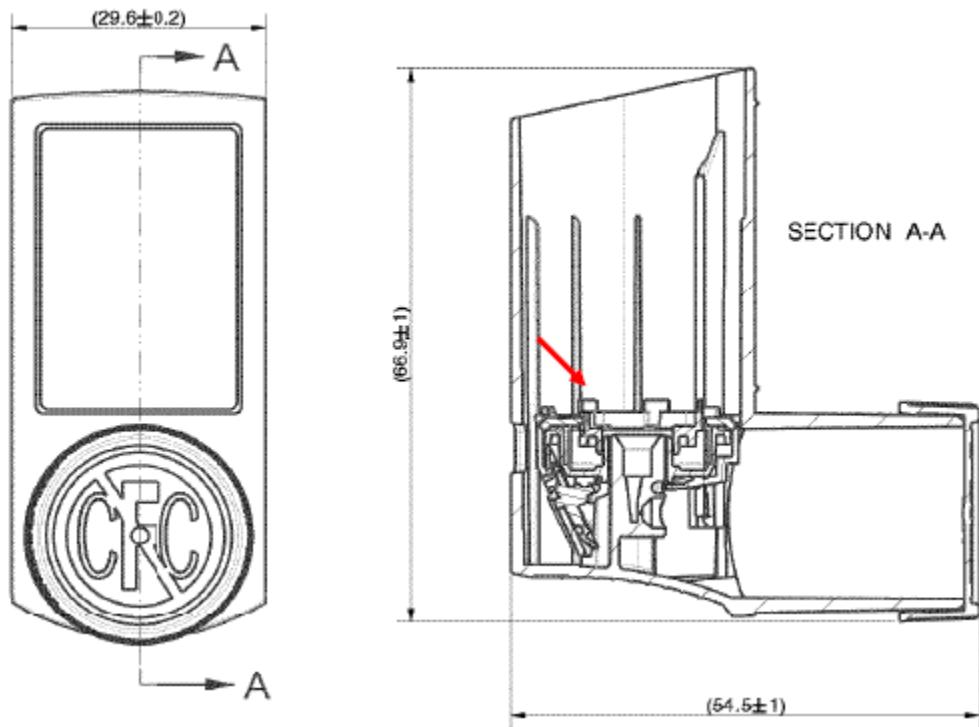
Aurobindo



See, e.g., PTX-040 (AURO_BECL00001277, at -1289-90 (Pharmaceutical Development)); *see also* PTX-330 (AURO_BECL00005711, at -5813 (Container Closure System)); PTX-409 (Aurobindo ANDA Product Sample); PTX-410 (Aurobindo ANDA Product Sample).

24. Defendants' medicament canister is retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister.

Cipla



See, e.g., PTX-373-74 (CIPLA-BDI_0803837-38 (Design Drawings)); see also PTX-308 (CIPLA-BDI_0004411, at -637 (Pharmaceutical Development)); PTX-094 (CIPLA-BDI_0156595, at -595, -597 (Photographs)) PTX-411 (Cipla ANDA Product Sample); PTX-412 (Cipla ANDA Product Sample).

Dated: October 31, 2022

Respectfully submitted,

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